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EXAMINER	
LE, EMILY M	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/667,193	SEGAL ET AL.	
	Examiner	Art Unit	
	Emily Le	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 10-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1-16 are pending. Claim 9 is withdrawn from examination because the claim is directed to a ligand for CD40, and not a ligand for a cytokine receptor as elected. Claims 1-8 and 10-16 are under examination.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In response to the rejection, Applicant submits that it is well known in the art, as evidenced by Exhibits A-J, which amino acids of GM-CSF molecules are necessary, and which are not necessary for receptor binding and/or bioactivity.

Applicant's submission has been considered, however, it is not found persuasive. The instant rejection is directed at the limitation recited in the cited claim, wherein the second amino acid sequence has at least five contiguous amino acids of GM-CSF.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient description of a representative number

of species by i) actual reduction to practice, ii) reduction to drawings, or iii) disclosure of relevant identifying characteristics. Examples of factors to be considered for the latter requirement include: a) disclosure of complete or partial structure, b) physical and/or chemical properties, c) functional characteristics, d) correlation between structure and function, and e) methods of making.

Each of the listed criteria is addressed in turn below.

i) sufficient description of a representative number of species by actual reduction to practice: The specification does not set forth the amino acid sequence of GM-CSF. The specification does not teach of a single amino acid sequence that is less that the complete GM-CSF polypeptide. Ergo, the specification does not provide for sufficient number of species by actual reduction to practice.

ii) sufficient description of a representative number of species by reduction to drawings: The specification does not contain any drawings. Thus, there is insufficient description of a representative number of species by reduction to drawings.

iii) sufficient description of a representative number of species by disclosure of relevant identifying characteristics: a) disclosure of complete or partial structure: The complete structure of the naturally occurring GM-CSF polypeptide is not provided in the specification, however, the Office recognizes that the complete amino acid sequence of GM-CSF can be readily ascertain from the art—as further evidenced by Exhibits A-J submitted by Applicant; b) physical and/or chemical properties: the claims require that the polypeptide have at least 5 amino acids sequence derived from GM-CSF, however, neither the claims nor the specification set forth any guidance pertaining to which amino

acid fragments to use with the claimed invention; c) functional characteristics: no function is specified in the claims or the specification; d) correlation between structure and function: no structural and functional correlation can be ascertained because neither the claims nor the specification set forth a function for the polypeptide.

In the instant, Applicant has taught only the full length GM-CSF polypeptide. Applicant has not set forth any teachings demonstrating that Applicant was in possession of any GM-CSF fragments comprising at least 5 amino acids. There is nothing provided in the specification that would lead the skilled artisan to recognize that Applicant was in possession of anything more than the full length GM-CSF polypeptide. Hence, the claim is rejected under 35 U.S.C. 112, first paragraph, written description, for insufficient possession of a single GM-CSF fragment comprising at least 5 amino acids.

Double Patenting

4. In response to the double patenting rejections set forth in the previous office action, and restated below, Applicant submits that a terminal disclaimer will be timely filed upon notification of allowable subject matter by the Office.

Applicant's intention is noted. However, until the rejections are properly addressed, with the submission of a terminal disclaimer, all double patenting rejections are maintained for the reason(s) set forth in the record.

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-8 and 10-16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 10/666833.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a method of modulating the immune response in an animal comprising the administration of a composition comprising a cell and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence comprising a cell-surface

binding moiety, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The broadest claim presented for the conflicting patent application is claim 1. Claim 1 is directed to a vaccine composition comprising an antigen bearing target and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence which can bind to a carbohydrate, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The difference between the two claims is the recitations "cell" and "antigen bearing target".

However, the recitation "cell" does fall entirely within the scope of the recitation "antigen bearing target". Thus, this aspect of the claim is anticipated by those recited in the conflicting patent application.

The other difference noted between the two claims is the recitations "first amino acid sequence which can bind to a carbohydrate" and "first amino acid sequence comprising a cell-surface binding moiety".

However, carbohydrate is a cell-surface binding moiety. Ergo, it would have been prima facie obvious for one on ordinary skill in the art at the time the invention was made to use a carbohydrate binding domain as cell surface binding moiety.

Additionally, the last difference between the two claims is that the claims in the instant application is directed at method of using the same product as those provided in the conflicting patent application.

However, claim 1 of the conflicting patent application contains language that suggests or makes optional the use of the claimed composition as a vaccine. Thus, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to administer the composition of the conflicting patent application to a subject, and the administration of the composition would necessarily modulate the subject's immune system.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claims 1-8 and 10-16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application No. 10/666886.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a method of modulating the immune response in an animal comprising the administration of a composition comprising a cell and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence comprising a cell-surface binding moiety, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The broadest claim presented for the conflicting patent application is claim 1. Claim 1 is directed to a method of modulating the immune response in an animal comprising the administration of a composition comprising a cell and a fusion

polypeptide. The fusion polypeptide comprise a first amino acid sequence comprising a cell-surface binding moiety, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The difference between the two claims is that the claims in the instant application is that the claims in the instant application is directed at method of using the same product as those provided in the conflicting patent application.

However, claim 1 of the conflicting patent application contains language that suggests or makes optional the use of the claimed composition as a vaccine. Thus, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to administer the composition of the conflicting patent application to a subject, and the administration of the composition would necessarily modulate the subject's immune system.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 1-8 and 10-16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-78 of copending Application No. 10/645000.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a method of modulating the immune response in an animal comprising the administration of a composition comprising a cell and a fusion polypeptide. The

fusion polypeptide comprise a first amino acid sequence comprising a cell-surface binding moiety, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The broadest claim presented for the conflicting patent application is claim 1. Claim 1 is directed to a vaccine composition comprising an antigen bearing target and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence which can bind to a carbohydrate, and a second amino acid sequence that is of a ligand for a cell surface polypeptide, wherein the ligand is selected from the group consisting of a ligand for a cytokine receptor, a ligand for CD40, a ligand for an adhesion molecule, a ligand for a defensin receptor, a ligand for heat shock protein receptor, a ligand for a T cell costimulatory molecule, a ligand for a counterreceptor for a T cell costimulatory molecule.

The difference between the two claims is the recitations "cell" and "antigen bearing target".

However, the recitation "cell" does fall entirely within the scope of the recitation "antigen bearing target". Thus, this aspect of the claim is anticipated by those recited in the conflicting patent application.

The other difference noted between the two claims is the recitations "first amino acid sequence which can bind to a carbohydrate" vs. "first amino acid sequence comprising a cell-surface binding moiety".

However, a carbohydrate is a cell-surface binding moiety. Ergo, it would have been prima facie obvious for one on ordinary skill in the art at the time the invention was made to use a carbohydrate binding domain as cell surface binding moiety.

Another difference noted between the two claims is the recitations "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte" and "a second amino acid sequence that is of a ligand for a cell surface polypeptide, wherein the ligand is selected from the group consisting of a ligand for a cytokine receptor, a ligand for CD40, a ligand for an adhesion molecule, a ligand for a defensin receptor, a ligand for heat shock protein receptor, a ligand for a T cell costimulatory molecule, a ligand for a counterreceptor for a T cell costimulatory molecule."

However, the ligands recited in claim 1 of the conflicting patent applications are all ligands for a cell surface polypeptide of a leukocyte. In the instant, claim 1 of the conflicting patent application falls entirely within the scope of claim 1 of the examined claimed. Hence, claim 1 of the conflicting patent application anticipates this aspect of the claim 1 of the instant patent application.

Additionally, the last difference between the two claims is that the claims in the instant application is that the claims in the instant application is directed at method of using the same product as those provided in the conflicting patent application.

However, claim 1 of the conflicting patent application contains language that suggests or makes optional the use of the claimed composition as a vaccine. Thus, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to administer the composition of the conflicting patent application to

a subject, and the administration of the composition would necessarily modulate the subject's immune system.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 1-8 and 10-16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of copending Application No. 10/224661, in view of Wortham et al. [1] and Faulkner et al.[2]

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a method of modulating the immune response in an animal comprising the administration of a composition comprising a cell and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence comprising a cell-surface binding moiety, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The broadest claim presented for the conflicting patent application is claim 1. Claim 1 is directed to a fusion polypeptide comprising a lectin that is capable of binding a carbohydrate and includes the HA carbohydrate binding domain of an influenza virus hemagglutinin and a naturally occurring GM-CSF molecule.

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[1] Wortham et al. Enhanced protective antibody responses to PspA after intranasal or subcutaneous injections of PspA genetically fused to granulocyte-macrophage colony-stimulating factor or interleukin-2. Infection and Immunity, 1998, Vol. 66, No. 4, 1513-1520.

[2] Faulkner et al. IL-2 linked to a peptide from influenza hemagglutinin enhances T cell activation by affecting the antigen-presentation function of bone marrow-derived dendritic cells. International Immunology, 2001, Vol. 13, No. 6, 713-721.

The difference between the two claims is the recitation "a first amino acid sequence comprising a cell-surface binding moiety" and "lectin that is capable of binding a carbohydrate and includes the HA carbohydrate binding domain of an influenza virus hemagglutinin".

However, the lectin that is capable of binding a carbohydrate and includes the HA carbohydrate binding domain of an influenza virus hemagglutinin is the first amino acid sequence comprising a cell-surface binding moiety.

The other difference between the two claims is the recitation "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte" and "a naturally occurring GM-CSF molecule".

However, the naturally occurring GM-CSF molecule is the second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The difference between the two sets of claims that claim 1 of the conflicting patent application does not recite the presence of a cell with the fusion polypeptide.

However, the art teaches the use of compositions such as those recited in claim 1 of the conflicting patent application as adjuvants in vaccines, as evidenced by Faulkner et al. [Page 713]

Thus, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to include a cell, e.g., autologous tumor cells, with the composition of the conflicting patent application. One of ordinary skill in the art would have been motivated to do so to boost the immune response to the tumor antigen.

Additionally, the last difference between the two claims is that the claims in the instant application is that the claims in the instant application is directed at method of using the same product as those provided in the conflicting patent application.

However, it has been demonstrated in the art that the administration of a fusion polypeptide that is the same as those recited in claim 1 of the conflicting patent provides an enhancing effect on the immune system, see Wortham et al. Wortham et al. provides that direct linkage of a cytokine to the antigen enhances the immune response. [page 1513] Thus, it would have been prima facie obvious for one of ordinary skill in the art to administer the composition recited in claim 1 of the conflicting patent application to a subject to enhance the subject's immune response against the antigen.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 1-8 and 10-16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-69 of copending Application No. 10/666898 , in view of Wortham et al. and Faulkner et al.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a method of modulating the immune response in an animal comprising the administration of a composition comprising a cell and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence comprising a cell-surface

binding moiety, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The broadest claim presented for the conflicting patent application is claim 1. Claim 1 is directed to a nucleic acid composition encoding a fusion polypeptide comprising a carbohydrate binding domain, and a ligand for a cell surface polypeptide.

The difference between the two claims is the recitations "first amino acid sequence comprising a cell-surface binding moiety" and "carbohydrate binding domain".

However, a carbohydrate binding domain is encompassed by the generic recitation "first amino acid sequence comprising a cell-surface binding moiety".

The other difference noted between the two claims is the recitations "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte" and "a ligand for a cell surface polypeptide".

However, the "a ligand for a cell surface polypeptide" is encompassed by the generic recitation "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte".

The difference between the two sets of claims that claim 1 of the conflicting patent application does not recite the presence of a cell with the fusion polypeptide.

However, the art teaches the use of compositions such as those recited in claim 1 of the conflicting patent application as adjuvants in vaccines, as evidenced by Faulkner et al. [Page 713]

Thus, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to include a cell, e.g., autologous tumor cells, with the

composition of the conflicting patent application. One of ordinary skill in the art would have been motivated to do so to boost the immune response to the tumor antigen.

Additionally, the last difference between the two claims is that the claims in the instant application is that the claims in the instant application is directed at method of using the same product as those provided in the conflicting patent application.

However, it has been demonstrated in the art that the administration of a fusion polypeptide that is the same as those recited in claim 1 of the conflicting patent provides an enhancing effect on the immune system, see Wortham et al. Wortham et al. provides that direct linkage of a cytokine to the antigen enhances the immune response. [page 1513] Thus, it would have been prima facie obvious for one of ordinary skill in the art to administer the composition recited in claim 1 of the conflicting patent application to a subject to enhance the subject's immune response against the antigen.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claims 1-8 and 10-16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-147 of copending Application No. 10/666885, in view of Wortham et al. and Faulkner et al.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a method of modulating the immune response in an animal comprising the administration of a composition comprising a cell and a fusion polypeptide. The

fusion polypeptide comprise a first amino acid sequence comprising a cell-surface binding moiety, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The broadest claim presented for the conflicting patent application is claim 1. Claim 1 is directed to a vector comprising a nucleic acid molecule composition encoding a fusion polypeptide comprising a carbohydrate binding domain, and a ligand for a cell surface polypeptide.

The difference between the two claims is the recitations "first amino acid sequence comprising a cell-surface binding moiety" and "carbohydrate binding domain".

However, a carbohydrate binding domain is encompassed by the generic recitation "first amino acid sequence comprising a cell-surface binding moiety".

The other difference noted between the two claims is the recitations "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte" and "a ligand for a cell surface polypeptide".

However, the "a ligand for a cell surface polypeptide" is encompassed by the generic recitation "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte".

The difference between the two sets of claims that claim 1 of the conflicting patent application does not recite the presence of cell with the fusion polypeptide.

However, the art teaches the use of compositions such as those recited in claim 1 of the conflicting patent application as adjuvants in vaccines, as evidenced by Faulkner et al. [Page 713]

Thus, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to include a cell, e.g. autologous tumor cells, with the composition of the conflicting patent application. One of ordinary skill in the art would have been motivated to do so to boost the immune response to the tumor antigen.

The last difference noted between the two is that claim 1 of the instant patent application is directed at a fusion polypeptide, and claim 1 of the conflicting patent application is directed at a vector construct comprising a nucleic acid composition that encodes the instantly claimed fusion polypeptide.

However, it would have been prima facie obvious for one of ordinary skill in the art to place the vector expression construct in a cell to express/make the fusion polypeptide. Furthermore, it would have been prima facie obvious for one of ordinary skill in the art to administer the construct to a subject because the art teaches that the administration of a cytokine construct enhance humoral as well as cell-mediated responses. [page 1513 of Wortham et al.]

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 1-8 and 10-16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-68 of copending Application No. 10/666871, in view of Wortham et al. and Faulkner et al.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a method of modulating the immune response in an animal comprising the administration of a composition comprising a cell and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence comprising a cell-surface binding moiety, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The broadest claim presented for the conflicting patent application is claim 1. Claim 1 is directed to a fusion polypeptide comprising a carbohydrate binding domain, and a ligand for a cell surface polypeptide.

The difference between the two claims is the recitations "first amino acid sequence comprising a cell-surface binding moiety" and "carbohydrate binding domain".

However, a carbohydrate binding domain is encompassed by the generic recitation "first amino acid sequence comprising a cell-surface binding moiety".

The other difference noted between the two claims is the recitations "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte" and "a ligand for a cell surface polypeptide".

However, the "a ligand for a cell surface polypeptide" is encompassed by the generic recitation "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte".

The difference between the two sets of claims that claim 1 of the conflicting patent application does not recite the presence of cell with the fusion polypeptide.

However, the art teaches the use of compositions such as those recited in claim 1 of the conflicting patent application as adjuvants in vaccines, as evidenced by Faulkner et al. [Page 713]

Thus, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to include a cell, e.g. autologous tumor cells, with the composition of the conflicting patent application. One of ordinary skill in the art would have been motivated to do so to boost the immune response to the tumor antigen.

The last difference noted between the two is that claim 1 of the instant patent application is directed at the administration of a fusion polypeptide, and claim 1 of the conflicting patent application is directed at a nucleic acid composition that encodes the instantly claimed fusion polypeptide.

However, it would have been prima facie obvious for one of ordinary skill in the art to administer the construct to a subject because the art teaches that the administration of a cytokine construct enhance humoral as well as cell-mediated responses. [page 1513 of Wortham et al.]

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. Claims 1-8 and 10-16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-77 of copending Application No. 10/666834, in view of Wortham et al.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a method of modulating the immune response in an animal comprising the administration of a composition comprising a cell and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence comprising a cell-surface binding moiety, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The broadest claim presented for the conflicting patent application is claim 1. Claim 1 is directed to a composition comprising an antigen bearing target and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence which can bind to a carbohydrate, and a second amino acid sequence that is of a ligand for a cell surface polypeptide. And the antigen bearing target comprises at least one of the following: a viral antigen, a bacterial antigen, a fungal antigen, a parasite antigen, a prion antigen.

The difference between the two claims is the recitations "cell" and "antigen bearing target".

However, the recitation "cell" does fall entirely within the scope of the recitation "antigen bearing target". Thus, this aspect of the claim is anticipated by those recited in the conflicting patent application.

The other difference noted between the two claims is the recitations "first amino acid sequence comprising a cell-surface binding moiety" and " first amino acid sequence which can bind to a carbohydrate".

However, "first amino acid sequence which can bind to a carbohydrate" falls entirely within the scope of the recitation "first amino acid sequence comprising a cell-surface binding moiety".

The other difference noted between the two claims is the recitations "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte" and "a ligand for a cell surface polypeptide".

However, the "a ligand for a cell surface polypeptide" is encompassed by the generic recitation "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte".

The difference between the two sets of claims that claim 1 of the conflicting patent application requires the antigen bearing target comprises at least one of the following: a viral antigen, a bacterial antigen, a fungal antigen, a parasite antigen, a prion antigen; whereas claim 1 of the instant patent application does not require the same.

However, the antigen bearing target of claim 1 of the instant patent application is generic to the an antigen bearing target comprises at least one of the following: a viral antigen, a bacterial antigen, a fungal antigen, a parasite antigen, a prion antigen of claim 1 of the conflicting patent application.

Additionally, the last difference between the two claims is that the claims in the instant application is that the claims in the instant application is directed at method of using the same product as those provided in the conflicting patent application.

However, it has been demonstrated in the art that the administration of a fusion polypeptide that is the same as those recited in claim 1 of the conflicting patent provides an enhancing effect on the immune system, see Wortham et al. Wortham et al. provides that direct linkage of a cytokine to the antigen enhances the immune response. [page 1513] Thus, it would have been prima facie obvious for one of ordinary skill in the art to administer the composition recited in claim 1 of the conflicting patent application to a subject to enhance the subject's immune response against the antigen.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

14. Claims 1-8 and 10-16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-77 of copending Application No. 10/6667166 in view of Wortham et al.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a method of modulating the immune response in an animal comprising the administration of a composition comprising a cell and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence comprising a cell-surface binding moiety, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The broadest claim presented for the conflicting patent application is claim 1. Claim 1 is directed to a composition comprising an antigen bearing target and a fusion

polypeptide. The fusion polypeptide comprise a first amino acid sequence which can bind to a carbohydrate, and a second amino acid sequence that is of a ligand for a cell surface polypeptide.

The difference noted between the two claims is the recitations "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte" and "a ligand for a cell surface polypeptide".

However, the "a ligand for a cell surface polypeptide" is encompassed by the generic recitation "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte".

The difference between the two claims is the recitations "cell" and "antigen bearing target".

However, the recitation "cell" does fall entirely within the scope of the recitation "antigen bearing target". Thus, this aspect of the claim is anticipated by those recited in the conflicting patent application.

The other difference noted between the two claims is the recitations "first amino acid sequence comprising a cell-surface binding moiety" and " first amino acid sequence which can bind to a carbohydrate".

However, "first amino acid sequence which can bind to a carbohydrate" falls entirely within the scope of the recitation "first amino acid sequence comprising a cell-surface binding moiety".

Additionally, the last difference between the two claims is that the claims in the instant application is that the claims in the instant application is directed at method of using the same product as those provided in the conflicting patent application.

However, it has been demonstrated in the art that the administration of a fusion polypeptide that is the same as those recited in claim 1 of the conflicting patent provides an enhancing effect on the immune system, see Wortham et al. Wortham et al. provides that direct linkage of a cytokine to the antigen enhances the immune response. [page 1513] Thus, it would have been prima facie obvious for one of ordinary skill in the art to administer the composition recited in claim 1 of the conflicting patent application to a subject to enhance the subject's immune response against the antigen.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. Claims 1-8 and 10-16 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-82 of copending Application No. 10/6668073.

Although the conflicting claims are not identical, they are not patentably distinct from each other because:

The broadest claim presented for the instant patent application is claim 1. Claim 1 is directed to a method of modulating the immune response in an animal comprising the administration of a composition comprising a cell and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence comprising a cell-surface

binding moiety, and a second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte.

The broadest claim presented for the conflicting patent application is claim 1. Claim 1 is directed to a method of modulating the immune response in an animal comprising the administration of a composition comprising an antigen bearing target and a fusion polypeptide. The fusion polypeptide comprise a first amino acid sequence which can bind to a carbohydrate, and a second amino acid sequence that is of a ligand for a cell surface polypeptide.

The difference noted between the two claims is the recitations "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte" and "a ligand for a cell surface polypeptide".

However, the "a ligand for a cell surface polypeptide" is encompassed by the generic recitation "second amino acid sequence that is of a ligand for a cell surface polypeptide of a leukocyte".

The difference between the two claims is the recitations "cell" and "antigen bearing target".

However, the recitation "cell" does fall entirely within the scope of the recitation "antigen bearing target". Thus, this aspect of the claim is anticipated by those recited in the conflicting patent application.

The other difference noted between the two claims is the recitations "first amino acid sequence comprising a cell-surface binding moiety" and " first amino acid sequence which can bind to a carbohydrate".

However, "first amino acid sequence which can bind to a carbohydrate" falls entirely within the scope of the recitation "first amino acid sequence comprising a cell-surface binding moiety".

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

16. No claims are allowed.

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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